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(54) **EYE THERAPY SYSTEM**

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USPC **607/53**

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USPC 607/53
See application file for complete search history.

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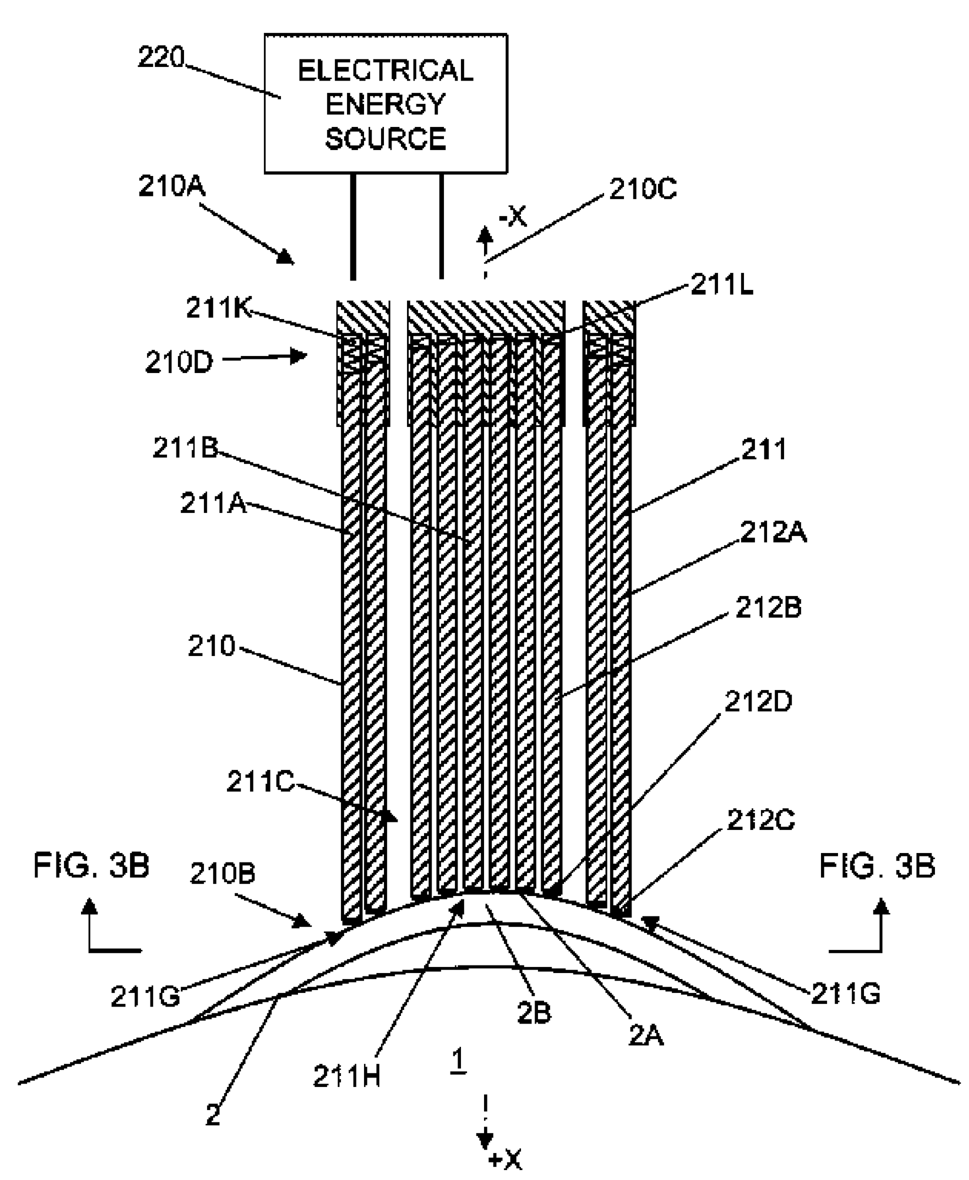
(57) **ABSTRACT**

An electrical energy applicator in one embodiment extends from a proximal end to a distal end. The energy conducting applicator includes, at the proximal end, a connection to one or more electrical energy sources. The energy conducting applicator directs electrical energy from the one or more electrical energy sources to the distal end. The energy conducting applicator includes an outer conductor and an inner conductor extending to the distal end. The outer conductor and the inner conductor are separated by a gap. The outer conductor includes a plurality of moveable outer segments and the inner conductor includes a plurality of moveable inner segments. The plurality of outer segments and the plurality of inner segments form a total contact surface at the distal end. The total contact surface is positionable at a surface of an eye. The electrical energy is applied to the eye according to the total contact surface.

33 Claims, 8 Drawing Sheets



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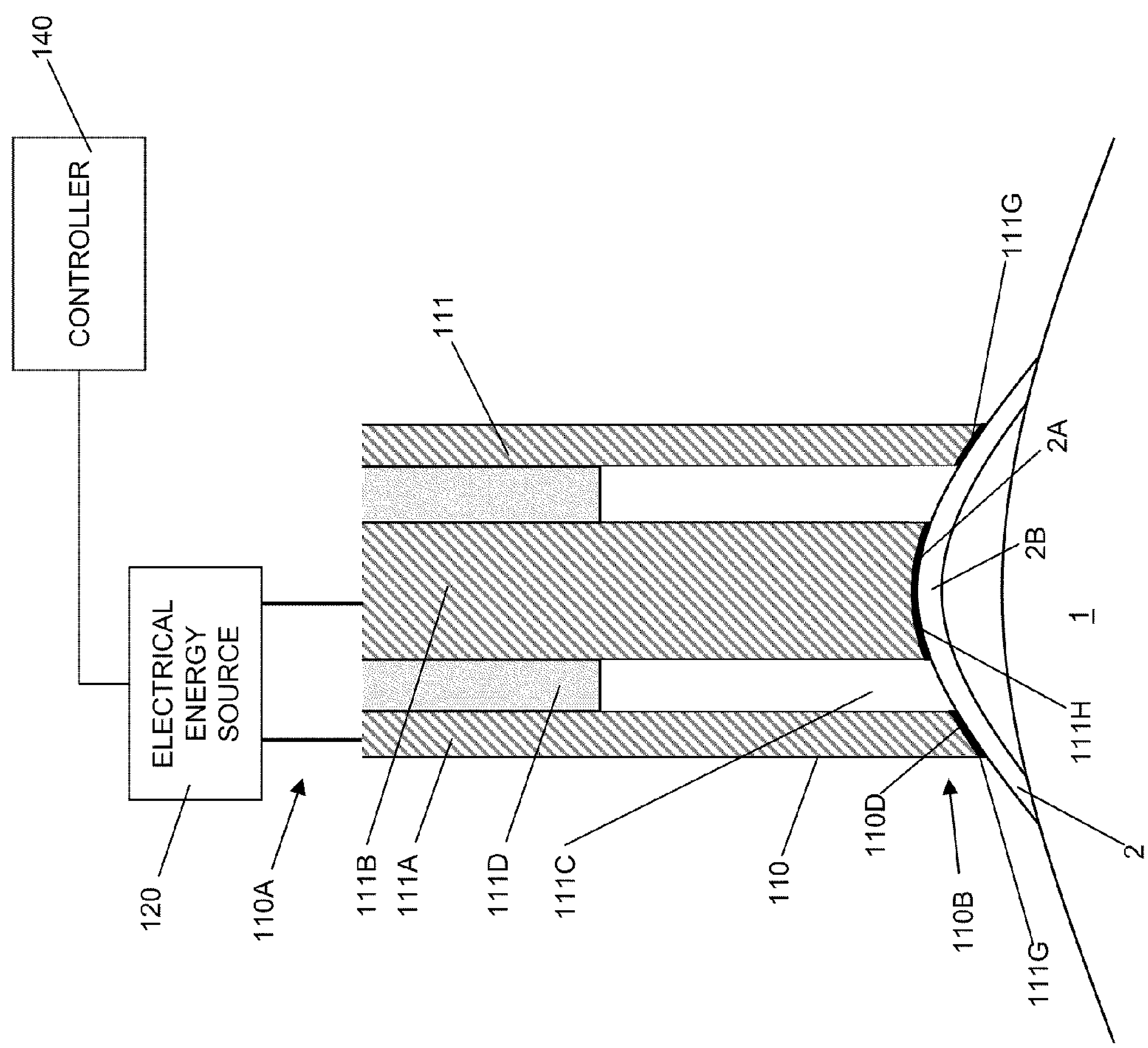
CONTROLLER
140
ELECTRICAL ENERGY SOURCE
120
110A
111
111A
111B
111C
111D
110
110D
110B
111G
111H
2A
2B
2
1

FIG. 1

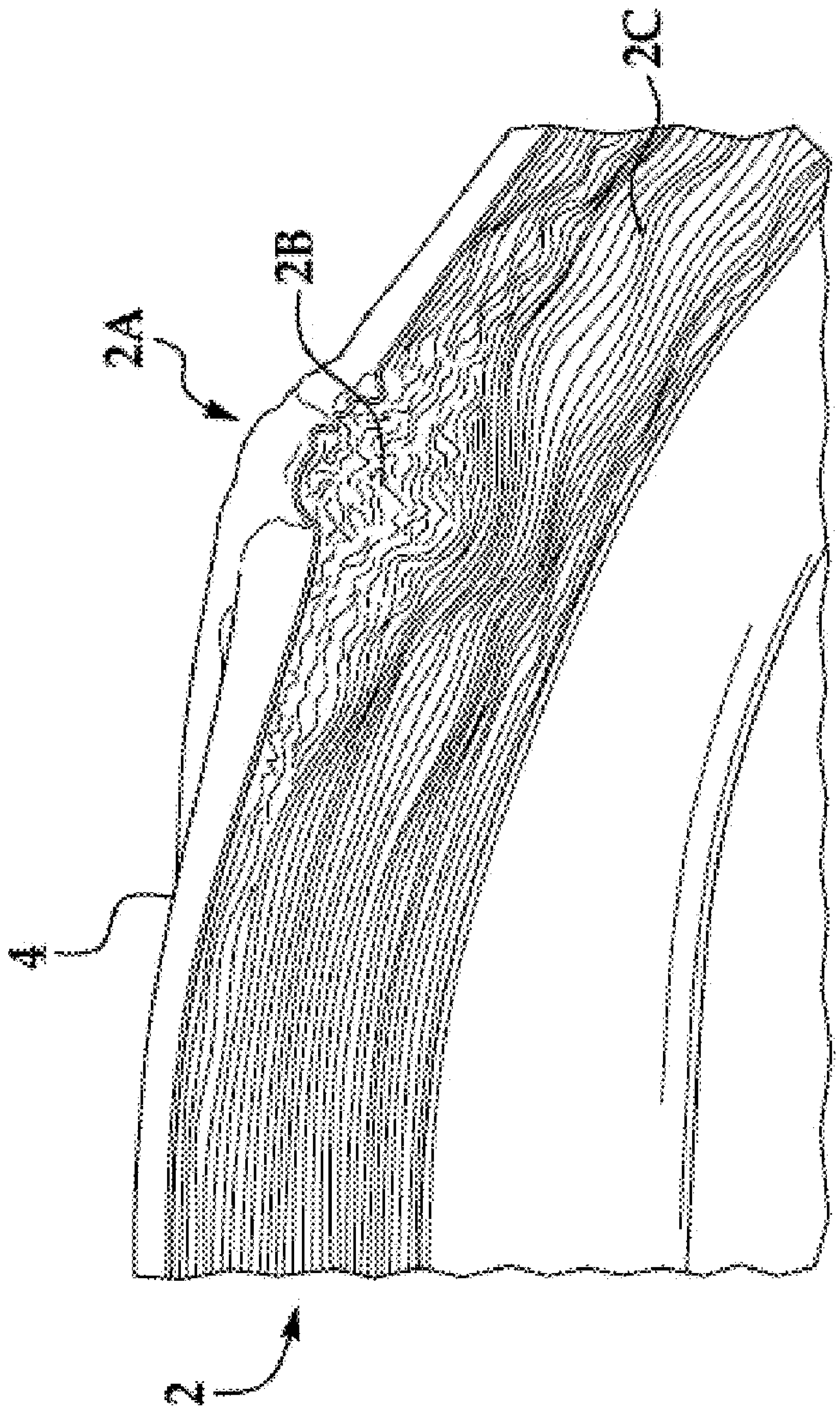

FIG. 2A

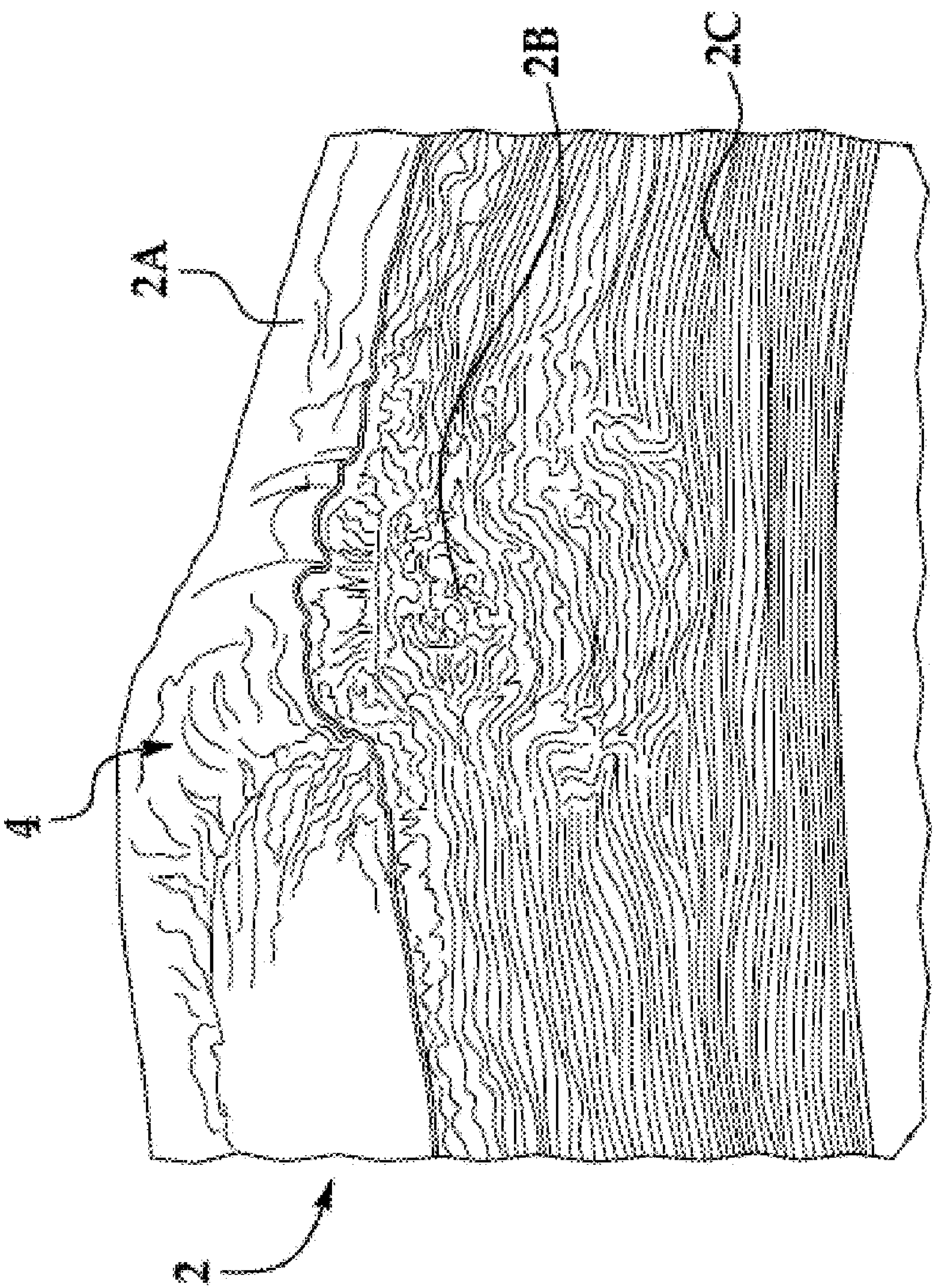

FIG. 2B

FIG. 2C

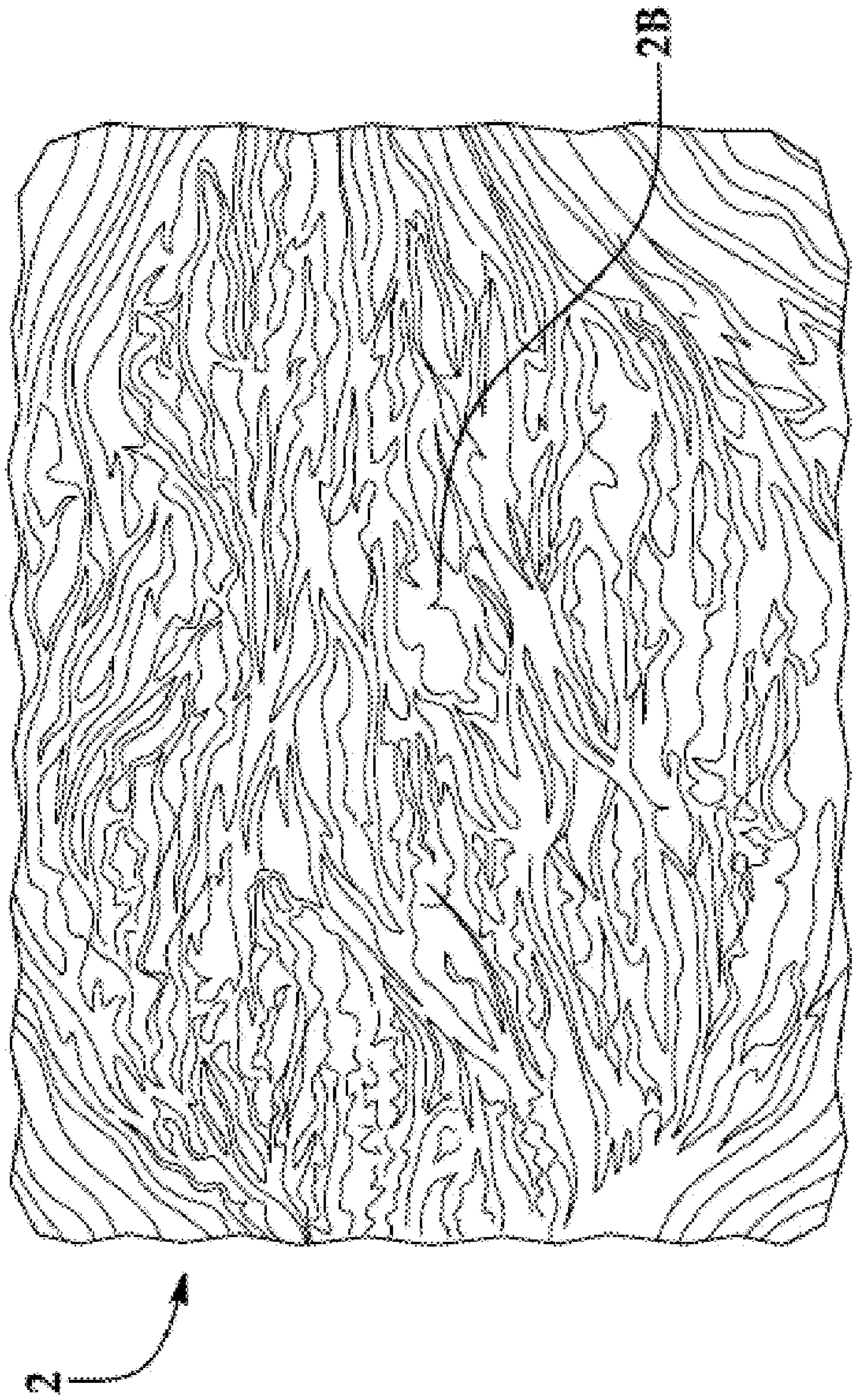

FIG. 2D

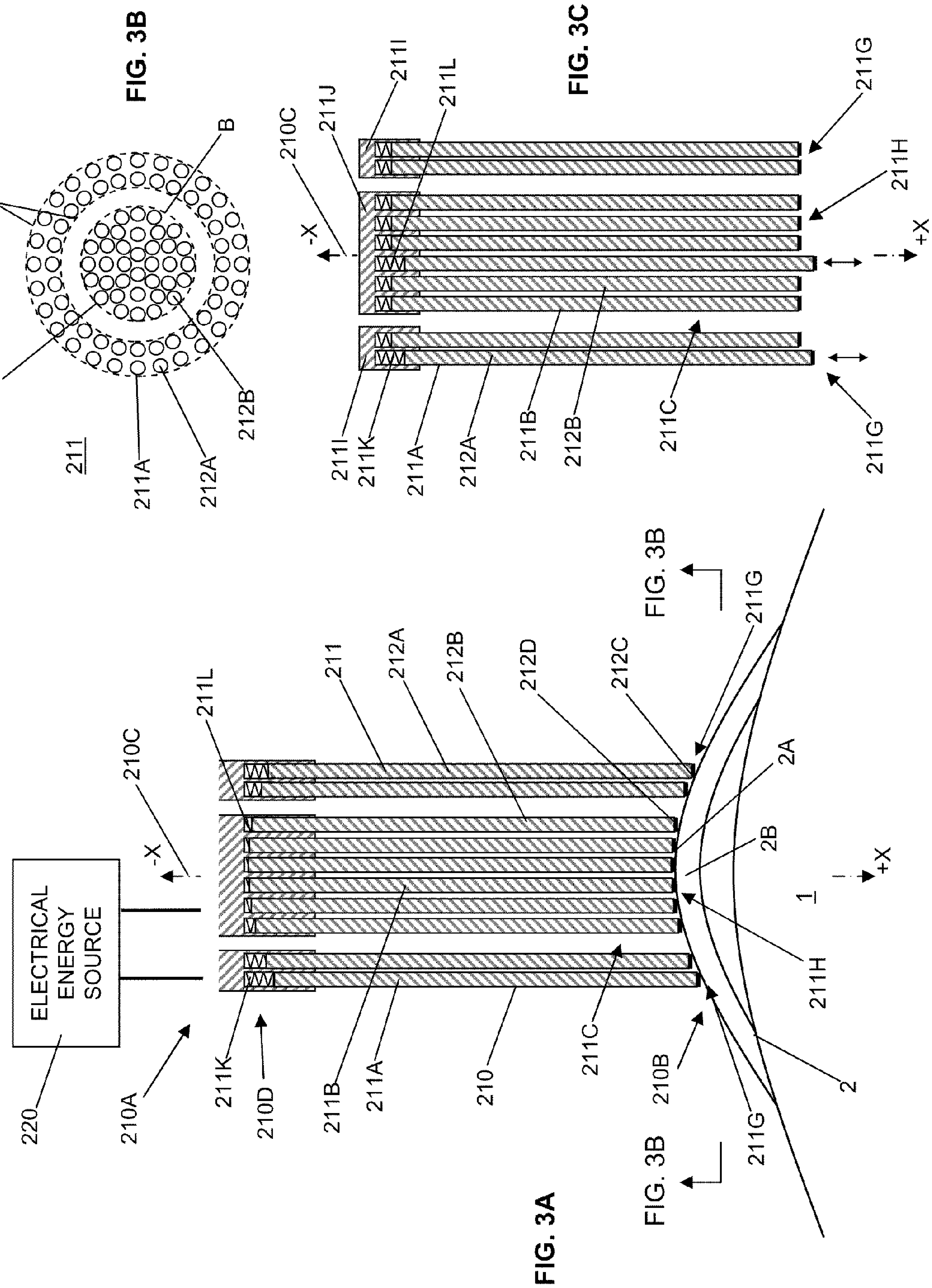

FIG. 3A

FIG. 3B

FIG. 3C

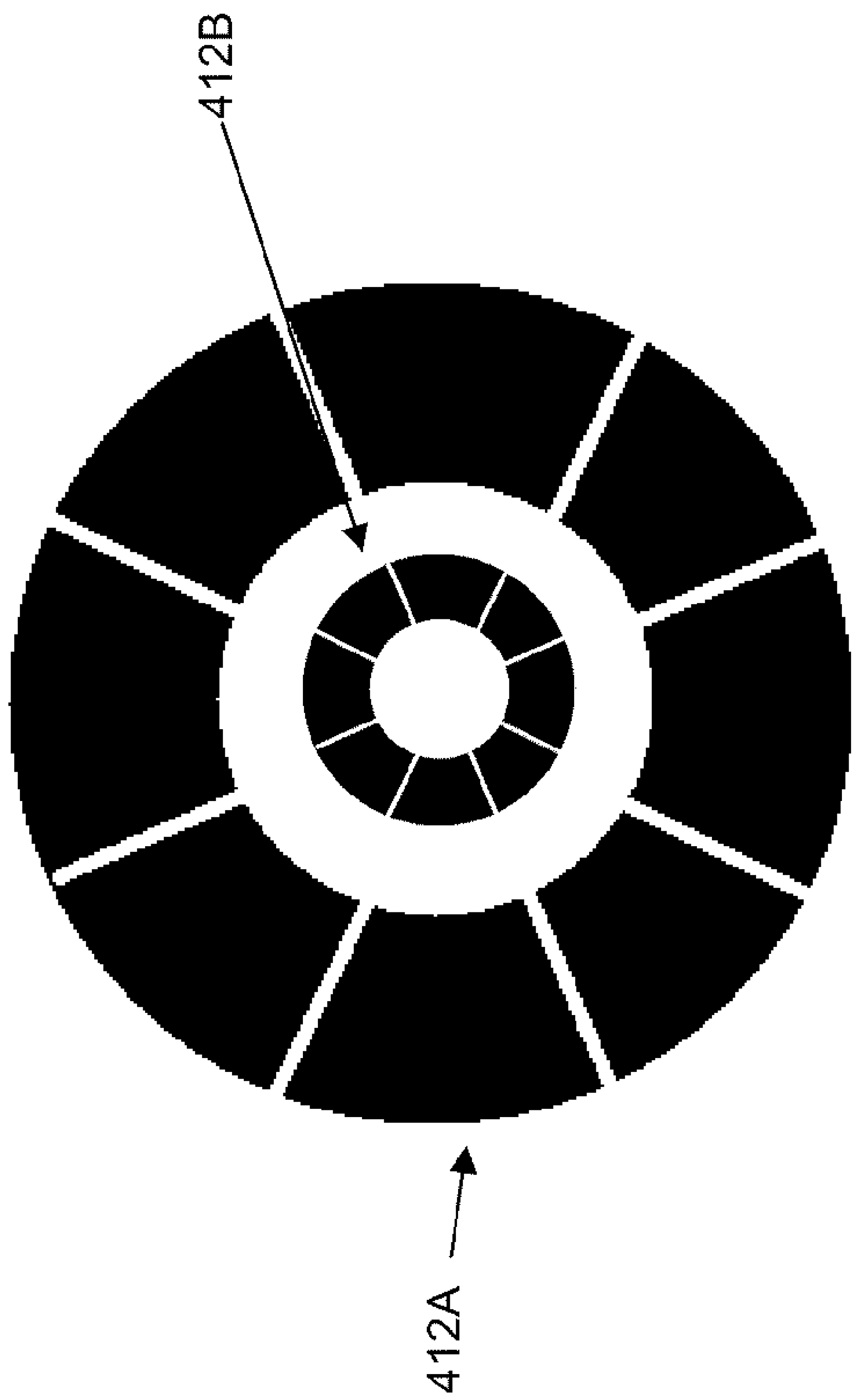

FIG. 4B

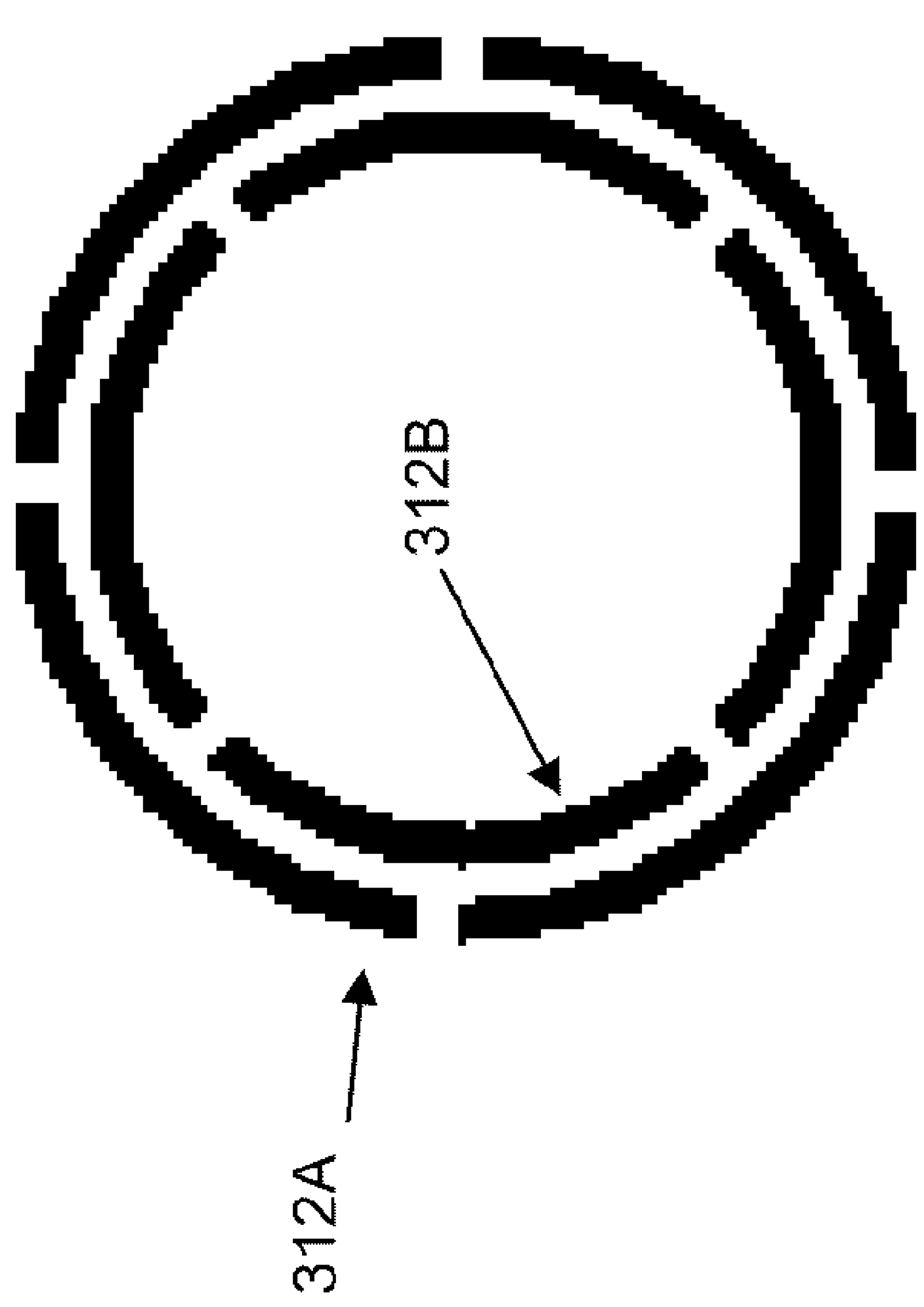

FIG. 4A

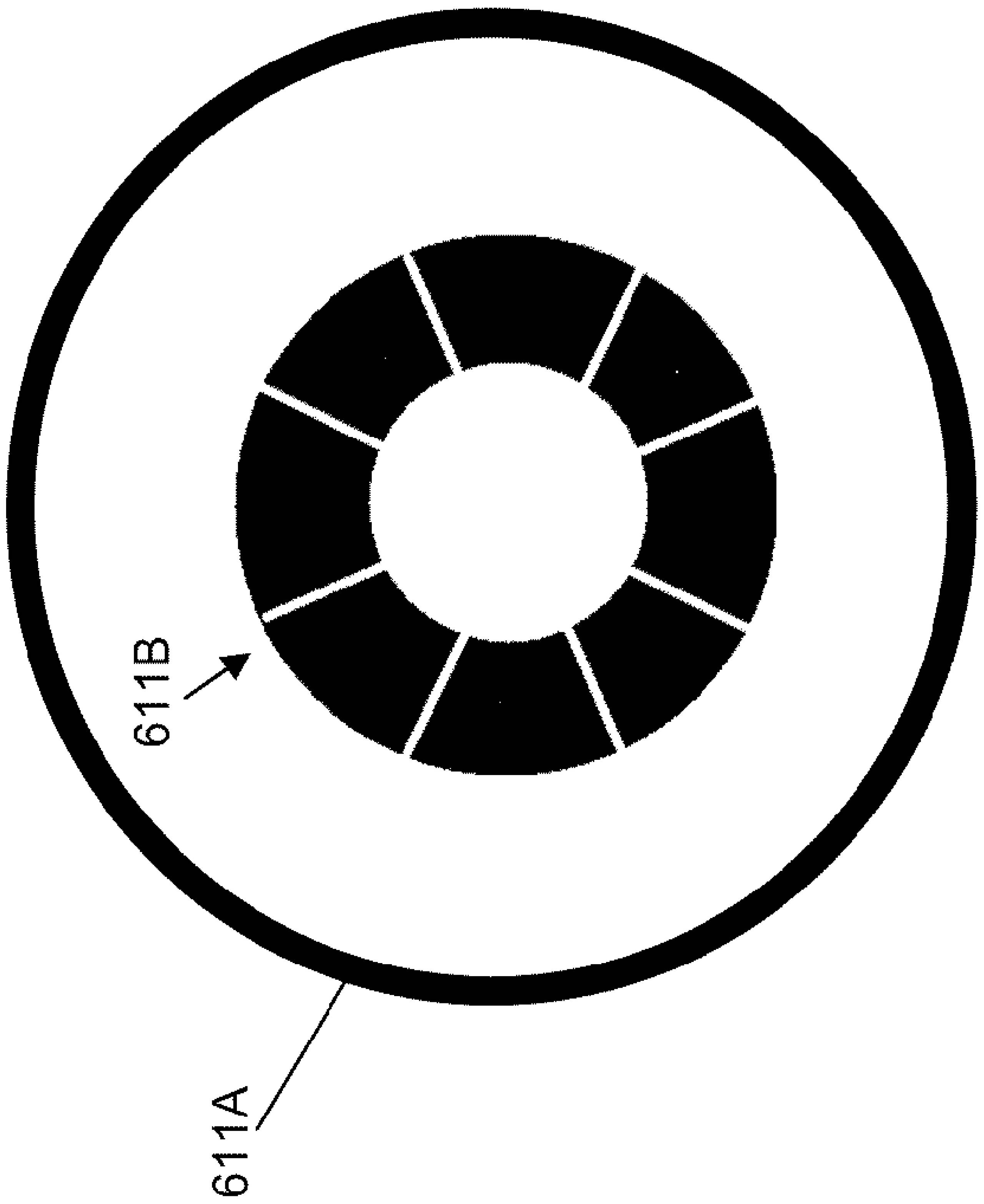

FIG. 4D

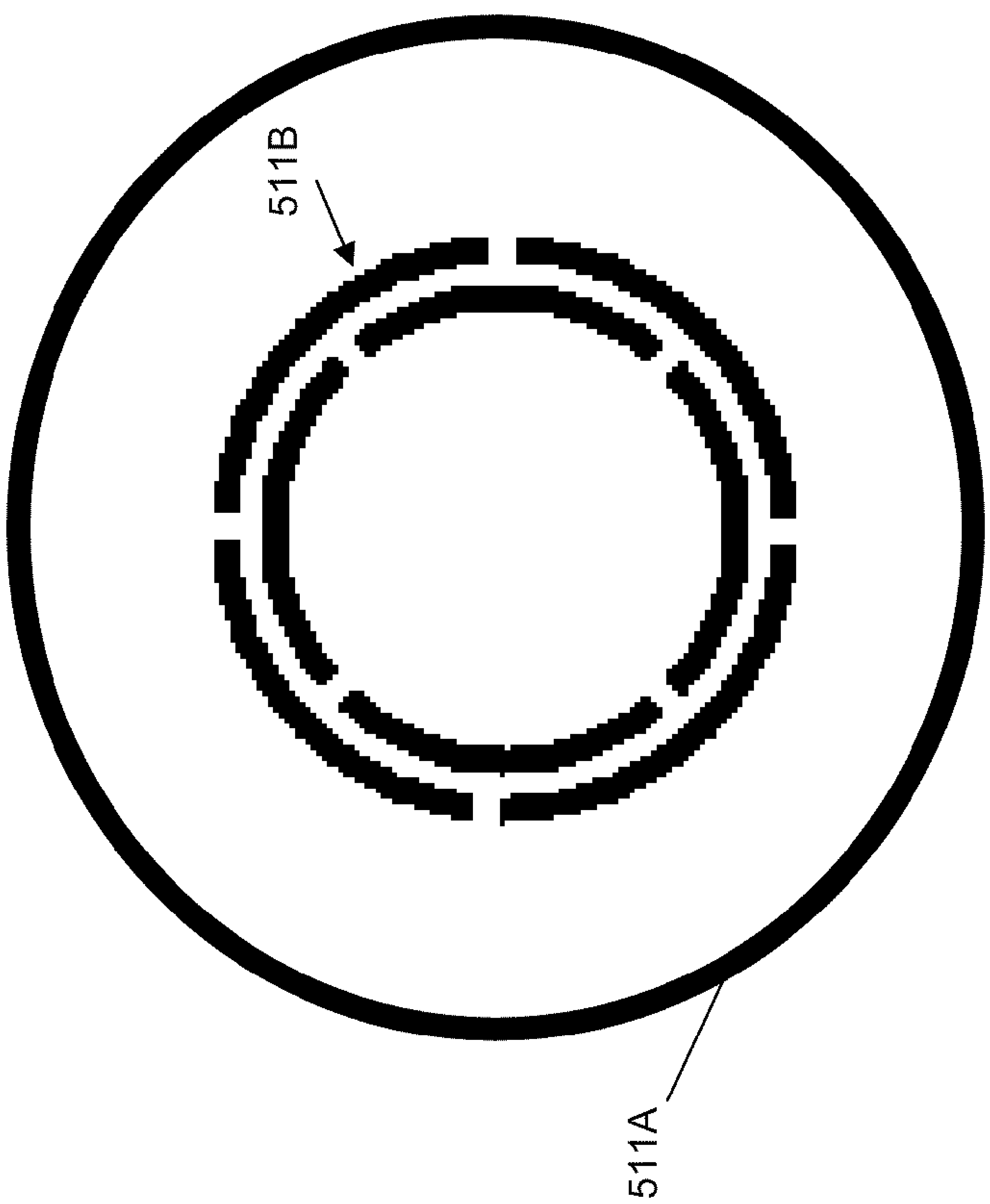

FIG. 4C

EYE THERAPY SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of priority from U.S. Provisional Application No. 61/166,002, filed Apr. 2, 2009, which is hereby incorporated by reference in its entirety.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention pertains to the field of keratoplasty and, more particularly, to a system configured to achieve adjustable contact with an eye to apply thermokeratoplasty.

2. Description of Related Art

A variety of eye disorders, such as myopia, keratoconus, and hyperopia, involve abnormal shaping of the cornea. Keratoplasty reshapes the cornea to correct such disorders. For example, with myopia, the shape of the cornea causes the refractive power of an eye to be too great and images to be focused in front of the retina. Flattening aspects of the cornea's shape through keratoplasty decreases the refractive power of an eye with myopia and causes the image to be properly focused at the retina.

Invasive surgical procedures, such as laser-assisted in-situ keratomileusis (LASIK), may be employed to reshape the cornea. However, such surgical procedures typically require a healing period after surgery. Furthermore, such surgical procedures may involve complications, such as dry eye syndrome caused by the severing of corneal nerves.

Thermokeratoplasty, on the other hand, is a noninvasive procedure that may be used to correct the vision of persons who have disorders associated with abnormal shaping of the cornea, such as myopia, keratoconus, and hyperopia. Thermokeratoplasty may be performed by applying electrical energy, for example, in the microwave band or radio frequency (RF) band. In particular, microwave thermokeratoplasty may employ a near field microwave applicator to apply energy to the cornea and raise the corneal temperature. At about 60° C., the collagen fibers in the cornea shrink. The onset of shrinkage is rapid, and stresses resulting from this shrinkage reshape the corneal surface. Thus, application of heat energy according to particular patterns, including, but not limited to, circular or annular patterns, may cause aspects of the cornea to flatten and improve vision in the eye.

SUMMARY

In general, the pattern of energy applied to a cornea during thermokeratoplasty depends on how the energy applicator is applied against the cornea. Embodiments according to aspects of the present invention account for the shape of the cornea when the applicator is positioned to deliver energy and can be selectively configured to apply energy to the cornea according to a selected pattern and/or penetration depth.

An electrical energy applicator in one embodiment extends from a proximal end to a distal end. The energy conducting applicator includes, at the proximal end, a connection to one or more electrical energy sources. The energy conducting applicator directs electrical energy from the one or more electrical energy sources to the distal end. The distal end is positionable at a surface of an eye. The energy conducting applicator includes an outer conductor and an inner conductor extending to the distal end. The outer conductor and the inner conductor are separated by a gap. The outer conductor includes a plurality of moveable outer segments and the inner conductor includes a plurality of moveable inner segments. The plurality of outer segments and the plurality of inner segments form a total contact surface at the distal end. The total contact surface is positionable at a surface of an eye. The electrical energy is applied to the eye according to the total contact surface.

In operation, the total contact surface area of the electrical energy applicator is positioned at a surface of an eye, and electrical energy is applied through the electrical energy conducting applicator to the eye according to the total contact surface.

These and other aspects of the present invention will become more apparent from the following detailed description of the preferred embodiments of the present invention when viewed in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** illustrates a system for applying heat to a cornea of an eye to cause reshaping of the cornea.

FIG. **2**A illustrates a high resolution image of a cornea after heat has been applied.

FIG. **2**B illustrates another high resolution image of the cornea of FIG. **2**A.

FIG. **2**C illustrates a histology image of the cornea of FIG. **2**A.

FIG. **2**D illustrates another histology image of the cornea of FIG. **2**A.

FIG. **3**A illustrates a view of a system that achieves adjustable contact between the energy conducting element and the eye according to aspects of the present invention.

FIG. **3**B illustrates a view of the energy conducting element of the system of FIG. **3**A.

FIG. **3**C illustrates another view of the energy conducting element of the system of FIG. **3**A.

FIG. **4**A illustrates a view of an energy conducting element according further aspects of the present invention.

FIG. **4**B illustrates a view of an energy conducting element according to still further aspects of the present invention.

FIG. **4**C illustrates a view of an energy conducting element according to still further aspects of the present invention.

FIG. **4**D illustrates a view of an energy conducting element according to still further aspects of the present invention.

DESCRIPTION

In general, the pattern of energy applied to a cornea during thermokeratoplasty depends on how the energy applicator is applied against the cornea. To apply the desired pattern of energy to the cornea, aspects of the present invention account for the shape of the cornea when the applicator is positioned to deliver energy. In particular, an energy conducting element of the applicator includes a plurality of movable segments that can adjust to the shape of the cornea. The plurality of movable segments therefore defines a total contact surface that corresponds to the shape of the cornea and provides the desired contact for the delivery of energy. The plurality of movable segments can also be selectively configured to apply energy to the cornea according to a selected pattern and/or penetration depth.

FIG. **1** illustrates an example system for applying energy to a cornea **2** of an eye **1** to generate heat and cause reshaping of the cornea. In particular, FIG. **1** shows an applicator **110** with an electrical energy conducting element **111** that is operably connected to an electrical energy source **120**, for example, via conventional conducting cables. The electrical energy conducting element **111** extends from a proximal end **110**A to a distal end **110**B of the applicator **110**. The electrical energy conducting element **111** conducts electrical energy from the source **120** to the distal end **110**B to apply heat energy to the cornea **2**, which is positioned at the distal end **110**B. In particular, the electrical energy source **120** may include a microwave oscillator for generating microwave energy. For example, the oscillator may operate at a microwave frequency range of about 400 MHz to about 3000 MHz, and more specifically at a frequency of around 915 MHz or around 2450 MHz, which has been safely used in other applications. As used herein, the term "microwave" may generally correspond to a frequency range from about 10 MHz to about 10 GHz.

As further illustrated in FIG. **1**, the electrical energy conducting element **111** may include two microwave conductors **111**A and **111**B, which extend from the proximal end **110**A to the distal end **110**B of the applicator **110**. In particular, the conductor **111**A may be a substantially cylindrical outer conductor, while the conductor **111**B may be a substantially cylindrical inner conductor that extends through an inner passage extending through the conductor **111**A. With the inner passage, the conductor **111**A has a substantially tubular shape. The outer conductors **111**A and the inner conductors **111**B may be formed, for example, of aluminum, stainless steel, brass, copper, other metals, coated metals, metal-coated plastic, metal alloys, combinations thereof, or any other suitable conductive material. Although other configurations are possible, FIG. **1** shows that the inner conductor **111**B may be recessed within the outer conductor **111**A to partially accommodate the shape of the cornea **2**.

With the concentric arrangement of conductors **111**A and **111**B, a substantially annular gap **111**C of a selected distance is defined between the conductors **111**A and **111**B. The annular gap **111**C extends from the proximal end **110**A to the distal end **110**B. A dielectric material **111**D may be used in portions of the annular gap **111**C to separate the conductors **111**A and **111**B. The distance of the annular gap **111**C between conductors **111**A and **111**B determines, in part, the penetration depth of microwave energy into the cornea **2** according to established microwave field theory. Thus, the energy conducting element **111** receives, at the proximal end **110**A, the electrical energy generated by the electrical energy source **120**, and directs microwave energy to the distal end **110**B, where the cornea **2** is positioned.

In general, the outer diameter of the inner conductor **111**B may be selected to achieve an appropriate change in corneal shape, i.e. keratometry, induced by the exposure to microwave energy. Meanwhile, the inner diameter of the outer conductor **111**A may be selected to achieve a desired gap between the conductors **111**A and **111**B. For example, the outer diameter of the inner conductor **111**B ranges from about 2 mm to about 10 mm while the inner diameter of the outer conductor **111**A ranges from about 2.1 mm to about 12 mm. In some systems, the annular gap **111**C may be sufficiently small, e.g., in a range of about 0.1 mm to about 2.0 mm, to minimize exposure of the endothelial layer of the cornea (posterior surface) to elevated temperatures during the application of energy by the applicator **110**.

A controller **140** may be employed to selectively apply the energy in the form of heat any number of times according to any predetermined or calculated sequence. In addition, the heat may be applied for any length of time. Furthermore, the magnitude of heat being applied to the cornea may also be varied. Adjusting such parameters for the application of heat determines the extent of changes that are brought about within the cornea **2**. Of course, the system attempts to limit the changes in the cornea **2** to an appropriate amount of shrinkage of collagen fibrils in a selected region and according to a selected pattern. When employing microwave energy to generate heat in the cornea **2**, for example with the applicator **110**, the microwave energy may be applied with low power (e.g., of the order of 40 W) and in long pulse lengths (e.g., of the order of one second). However, other systems may apply the microwave energy in short pulses. In particular, it may be advantageous to apply the microwave energy with durations that are shorter than the thermal diffusion time in the cornea **2**. For example, the microwave energy may be applied in pulses having a higher power in the range of about 500 W to about 3 kW and a pulse duration in the range of about 5 milliseconds to about one second.

Referring again to FIG. **1**, at least a portion of each of the conductors **111**A and **111**B may be coated or covered with an electrical insulator to minimize the concentration of electrical current in the area of contact between the corneal surface (epithelium) **2**A and the conductors **111**A and **111**B. In some systems, the conductors **111**A and **111**B, or at least a portion thereof, may be coated or covered with a material that can function both as an electrical insulator as well as a thermal conductor.

In the system illustrated in FIG. **1**, a dielectric layer **110**D is disposed along the distal end **111**B of the applicator **110** to protect the cornea **2** from electrical conduction current that would otherwise flow into the cornea **2** via conductors **111**A and **111**B. Such current flow may cause unwanted temperature effects in the cornea **2** and interfere with achieving a maximum temperature within the collagen fibrils in a mid-depth region **2**B of the cornea **2**. Accordingly, the dielectric layer **110**D is positioned between the conductors **111**A and **111**B and the cornea **2**. The dielectric layer **110**D may be sufficiently thin to minimize interference with microwave emissions and thick enough to prevent superficial deposition of electrical energy by flow of conduction current. For example, the dielectric layer **110**D may be a biocompatible material deposited to a thickness of about 20-100 micrometers, preferably about 50 micrometers. As another example, the dielectric layer **110**D can be a flexible sheath-like structure of biocompatible material that covers the conductors **111**A and **111**B at the distal end **110**B and extends over a portion of the exterior wall of the outer conductor **111**B. As still a further example, the dielectric layer **110**D can include a first flexible sheath-like structure of biocompatible material that covers the distal end of the inner conductor **111**A and a second flexible sheath-like structure of biocompatible material that covers the distal end of the outer conductor **111**B.

In general, an interposing layer, such as the dielectric layer **110**D, may be employed between the conductors **111**A and **111**B and the cornea **2** as long as the interposing layer does not substantially interfere with the strength and penetration of the microwave radiation field in the cornea **2** and does not prevent sufficient penetration of the microwave field and generation of a desired heating pattern in the cornea **2**. The dielectric material may be elastic (e.g., polyurethane, silastic, combinations thereof and/or the like) or nonelastic (e.g., Teflon®, polyimides, combinations thereof and/or the like). The dielectric material may have a fixed dielectric constant or varying dielectric constant by mixing materials or doping the sheet, the variable dielectric being spatially distributed so that it may affect the microwave hearing pattern in a customized way. The thermal conductivity of the material may have fixed thermal properties (e.g., thermal conductivity and/or specific heat), or may also vary spatially, through mixing of materials or doping, and thus provide a means to alter the heating pattern in a prescribed manner. Another approach for spatially changing the heating pattern is to make the dielectric sheet material of variable thickness. The thicker region will heat less than the thinner region and provides a further means of spatial distribution of microwave heating.

During operation, the distal end **110**B of the applicator **110** as shown in FIG. **1** is positioned on or near the corneal surface **2**A. Preferably, the applicator **110** makes direct contact with the corneal surface **2**A. In particular, such direct contact positions the conductors **111**A and **111**B at the corneal surface **2**A (or substantially near the corneal surface **2**A if there is a thin interposing layer between the conductors **111**A and **111**B and the corneal surface **2**A). Accordingly, direct contact helps ensure that the pattern of microwave heating in the corneal tissue has substantially the same shape and dimension as the gap **111**C between the two microwave conductors **111**A and **111**B.

The system of FIG. **1** is provided for illustrative purposes only, and other systems may be employed to apply heat to cause reshaping of the cornea. Other systems are described, for example, in U.S. patent application Ser. No. 12/208,963, filed Sep. 11, 2008, which is a continuation-in-part application of U.S. patent application Ser. No. 11/898,189, filed on Sep. 10, 2007, the contents of these applications being entirely incorporated herein by reference. As described in U.S. patent application Ser. No. 12/208,963, a cooling system may also be employed in combination with the applicator **110** to apply coolant to the cornea **2** and determine how the energy is applied to the cornea **2**.

FIGS. **2**A-D illustrate an example of the effect of applying heat to corneal tissue with a system for applying heat, such as the system illustrated in FIG. **1**. In particular, FIGS. **2**A and **2**B illustrate high resolution images of cornea **2** after heat has been applied. As FIGS. **2**A and **2**B show, a lesion **4** extends from the corneal surface **2**A to a mid-depth region **2**B in the corneal stroma **2**C. The lesion **4** is the result of changes in corneal structure induced by the application of heat as described above. These changes in structure result in an overall reshaping of the cornea **2**. It is noted that the application of heat, however, has not resulted in heat-related damage to the corneal tissue.

As further illustrated in FIGS. **2**A and **2**B, the changes in corneal structure are localized and limited to an area and a depth specifically determined by an applicator as described above. FIGS. **2**C and **2**D illustrate histology images in which the tissue shown in FIGS. **2**A and **2**B has been stained to highlight the structural changes induced by the heat. In particular, the difference between the structure of collagen fibrils in the mid-depth region **2**B where heat has penetrated and the structure of collagen fibrils outside the region **2**B is clearly visible. Thus, the collagen fibrils outside the region **2**B remain generally unaffected by the application of heat, while the collagen fibrils inside the region **2**B have been rearranged and formed new bonds to create completely different structures. In other words, unlike processes, such as orthokeratology, which compress areas of the cornea to reshape the cornea via mechanical deformation, the collagen fibrils in the region **2**B are in an entirely new state.

As shown in FIG. **1**, the energy conducting element **111** includes a contact surface **111**G at the distal end **110**B of the outer conductor **111**A and a contact surface **111**H at the distal end **110**B of the inner conductor **111**B. The contact surfaces **111**G and **111**H, or portions thereof, come into direct contact with the corneal surface **2**A. In general, the pattern of energy applied to the cornea **2** depends in part on the position of the contact surfaces **111**G and **111**H relative to the corneal surface **2**A. The contact surfaces **111**G and **111**H are shown to be contoured in FIG. **1**, but it is understood that the contact surfaces **111**G and **111**H may have other predetermined shapes.

Although the contact surfaces **111**G and **111**H may be designed to have a contoured shape, this predetermined shape may not correspond sufficiently to the actual shape of the corneal surface **2**A. Moreover, the contact surfaces **111**G and **111**H may be formed as integral surfaces from a rigid material, so that they cannot be dynamically changed to correspond more closely to the actual shape of the corneal surface **2**A. In general, the cost of providing a customized applicator, such as the applicator **110** in FIG. **1**, for each individual application may be prohibitive, so the contact surface **111**G and **111**H may be designed to approximate the general shape of the corneal surface **2**A as best as possible and to offer the broadest possible use. For example, the contact surfaces **111**G and **111**H may each be a single surface shaped according to a symmetric concave model of the cornea **2**. Because the actual shapes of corneal surfaces **2**A may vary according to different individuals, however, the contact surfaces **111**G and **111**H may not provide the desired contact between the energy conducting element **111** and the corneal surface **2**A. In some cases, individuals may have asymmetric corneas **2** which are likely to experience non-uniform contact when symmetric contact surfaces **111**G and **111**H are applied. Non-uniform contact may result in imprecise and inaccurate delivery of energy to the cornea **2** and may prevent the desired reshaping of the cornea **2**.

Furthermore, in some cases, the energy conducting element **111** is applied to the corneal surface **2**A to cause an observable amount of flattening, or applanation, of the cornea **2**. Although applanation may provide a good indication that contact between the contact surfaces **111**G and **111**H and the corneal surface **2**A has been achieved, pressure applied by the contact surfaces **111**G and **111**H may be non-uniform over the contact surfaces **111**G and **111**H if the shape of the contact surfaces **111**G and **111**H does not correspond sufficiently with the corneal surface **2**A. The application of non-uniform pressure against the corneal surface **2**A may produce mechanical deformation that may affect the results of thermokeratoplasty.

Systems and methods for causing applanation of the cornea are described in U.S. patent application Ser. No. 12/209,123, filed Sep. 11, 2008, which is a continuation-in-part application of U.S. patent application Ser. No. 12/018,457, filed on Jan. 23, 2008, and U.S. Provisional Patent Application No. 61/113,395, filed Nov. 11, 2008, the contents of these applications being entirely incorporated herein by reference. In addition, the effects of mechanical deformation during thermokeratoplasty are described, for example, in U.S. application Ser. No. 12/018,473, filed Jan. 23, 2008, the contents of which are entirely incorporated herein by reference.

To achieve a desired application of energy to the cornea, aspects of the present invention account for the shape of the cornea when the applicator is positioned to deliver energy. In particular, an energy conducting element of the applicator includes a plurality of movable segments that can adjust to the shape of the cornea when positioned against the cornea. The plurality of movable segments defines a total contact surface that corresponds to the shape of the cornea and provides the desired contact for the delivery of energy. Advantageously, the ability to adjust the shape of the total contact surface dynamically allows a single applicator design to be employed on varying corneal shapes.

FIGS. **3**A-C illustrate an embodiment of an applicator **210** with an energy conducting element **211** that provides adjustable contact with the cornea **2** of an eye **1**. Like the energy conducting element **111**, the energy conducting element **211** includes an outer conductor **211**A and an inner conductor **211**B that extend along a longitudinal axis **210**C from a proximal end **210**A to a distal end **210**B. However, the outer conductor **211**A is defined at the distal end **210**B by a plurality of outer conductor segments **212**A, and the inner conductor **211**B is defined at the distal end **210**B by a plurality of inner conductor segments **212**B. In other words, unlike the outer conductor **111**A and the inner conductor **111**B in FIG. **1**, the outer conductor **211**A and the inner conductor **211**B are each configured to contact the corneal surface **2**A with more than one component.

As shown in FIG. **3**A, the segments **212**A and **212**B may extend along the longitudinal axis **210**C from an intermediate section **210**D of the energy conducting element **211** to the distal end **210**B. In addition, as FIG. **3**B illustrates, the outer conductor segments **212**A may be organized within a region bounded by dashed lines A, which might generally correspond with the exterior walls of the outer conductor **111**A of FIG. **1**. Similarly, the inner conductor segments **212**B may be organized within a region bounded by dashed line B, which might generally correspond with the exterior walls of the inner conductor **111**B of FIG. **1**. In the example embodiment of FIGS. **3**A-C, the segments **212**A and **212**B may be formed as cylindrical or pin-like structures from electrically conducting materials.

Like the conductors **111**A and **111**B, aspects of the conductors **211**A and **211**B may be formed, for example, from aluminum, stainless steel, brass, copper, other metals, coated metals, metal-coated plastic, other metal alloys, combinations thereof or any other suitable conductive material. Although a specific number of segments **212**A and **212**B may be illustrated, it is contemplated that any number of segments **212**A and **212**B may be employed as long as the configuration provides the appropriate conducting characteristics for delivering energy to the cornea **2**.

Each of the segments **212**A includes a segment contact surface **212**C, and each of the segments **212**B includes a segment contact surface **212**D. Collectively, the segment contact surfaces **212**C define a total contact surface **211**G for the outer conductor **211**A, while the segment contact surfaces **212**D define a total contact surface **211**H for the inner conductor **211**B. The total contact surfaces **211**G and **211**H at the distal end **210**B of the outer conductor **211**A and the inner conductor **211**B, respectively, contact the corneal surface **2**A to deliver the energy to the cornea **2**.

As explained above, in some systems, the conductors **211**A and **211**B, or at least a portion thereof, may be coated with or covered by a material that can function both as an electrical insulator as well as a thermal conductor. The material may be a dielectric layer employed along the distal end **210**B of the applicator **210** to protect the cornea **2** from electrical conduction current that would otherwise flow into the cornea **2** via conductors **211**A and **211**B. The dielectric layer may be employed between the conductors **211**A and **211**B and the cornea **2** as long as the interposing layer does not substantially interfere with the strength and penetration of the microwave radiation field in the cornea **2** and does not prevent sufficient penetration of the microwave field and generation of a desired heating pattern in the cornea **2**. As an example, the dielectric layer can be a flexible sheath-like structure of biocompatible material that covers the conductors **211**A and **211**B at the distal end **210**B and extends over a portion of the exterior wall of the outer conductor **211**B. As another example, the dielectric layer can include a first flexible sheath-like structure of biocompatible material that covers the distal end of the inner conductor **211**A and a second flexible sheath-like structure of biocompatible material that covers the distal end of the outer conductor **211**B. As still a further example, the dielectric layer can be formed as a plurality of sheath-like structures that are individually positioned over the outer surface of each of the conductor segments **212**A and **212**B.

As shown in FIGS. **3**A-C, the segments **212**A and **212**B may be spaced apart from each other. However, the proximity of the segments **212**A allows the segments **212**A collectively to act as a single outer conductor, and the proximity of the segments **212**B allows the segments **212**B collectively to act as a single inner conductor. In particular, the segments **212**A may be arranged so that the effect of delivering energy through one segment **212**A extends across the spaces to adjacent segments **212**A, and the segments **212**B are arranged so that the effect of delivering energy through one segment **212**B extends across the spaces to adjacent segments **212**B.

Thus, the combination of the outer conductor **211**A and the inner conductor **211**B delivers energy from an energy source **220** to a distal end **210**B. As described previously, the energy is delivered to the cornea **2** in a pattern that depends, in part, on a gap **211**C at the distal end **210**B defined between the outer conductor **211**A and the inner conductor **211**B. In general, the energy conducting element **211** may be applied to the eye **1** in a manner similar to the energy conducting element **111** to generate heat and cause reshaping of the cornea **2**.

However, as illustrated in FIG. **3**C, each outer conductor segment **212**A can move along the longitudinal axis **210**C, relative to each of the other outer conductor segments **212**A. Similarly, each inner conductor segment **212**B can move along the longitudinal axis **210**C, relative to each of the other inner conductor segments **212**B. Thus, unlike the statically shaped contact surfaces **111**G and **111**H shown in FIG. **1**, the segments **212**A and **212**B are movable to define different shapes for total contact surfaces **211**G and **211**H, respectively. As shown in FIG. **3**A, the segments **212**A and **212**B may be moved so that the total contact surfaces **211**G and **211**H fit the actual shape of the corneal surface **2**A more closely.

In addition, FIGS. **3**A and **3**C show that the applicator **210** may employ biasing devices **211**K and **211**L that provide a slight bias in the +x direction against corresponding segments **212**A and **212**B. For example, the biasing devices **211**K and **211**L may be springs or a material with spring-like characteristics. In general, the biasing devices **211**K and **211**L provide a force in the +x direction according to a displacement in the −x direction (i.e., $F=-kx$, where F is the restoring force exerted by the biasing device in the +x direction, x is the displacement from equilibrium in the −x direction, and k is a force constant). Although gravity may be employed to force the segments **212**A and **212**B in the +x direction into contact with the cornea **2**, the biasing devices **211**K and **211**L may additionally or alternatively be employed to provide a force in the +x direction. The biasing devices **211**K and **211**L ensure that the segments **212**A and **212**B remain in contact with the corneal surface **2**A without creating an undesired level of pressure against the corneal surface **2**A that may affect the thermokeratoplasty. To reduce the risk of an undesired level of pressure against the corneal surface **2**A, the inner conductor segments **212**B may be recessed within the outer conductor segments **212**A (i.e., the inner conductor segments **212**B may be shorter than the outer conductor segments **212**A) or the biasing devices **211**K and **211**L may be configured such that the biasing force applied to the outer segments **212**A is greater than the biasing force applied to the inner segments **212**B. As further illustrated by FIGS. **3**A and **3**C, the biasing devices **211**K and **211**L may be employed in combination with the couplings **211**I and **211**J, respectively, where they can act on the ends of the corresponding segments **212**A and **212**B.

According to some embodiments, the applicator **210** can also include one or more devices for determining whether sufficient contact has been established between the applicator **210** (i.e., the individual conductor segments **212**A and **212**B) and the eye for accurate and precise delivery of energy to the eye. Such devices are described in U.S. application Ser. No. 12/617,544, filed Nov. 12, 2009, the contents of which being entirely incorporated herein by reference.

In operation, the energy conducting element **211** is moved in the +x direction to position each of the segments **212**A and **212**B against the corneal surface **2**A. During this process, some segments **212**A and **212**B may come into contact with the corneal surface **2**A, while the other segments **212**A and **212**B require further movement of the energy conducting element **211** in the +x direction to reach the corneal surface **2**A. For example, as shown in FIG. **3**A, the inner conductor segments **212**B may reach the corneal surface **2**A before the outer conductor segments **212**A, because the central region of the cornea **2** extends farther from the rest of the eye **1** and toward the oncoming energy conducting element **211**. As the energy conducting element **211** continues to move toward the cornea **2**, the corneal surface **2**A applies a reaction force against the segments **212**A and **212**B already in contact. This reaction force causes the corresponding segments **212**A and **212**B to move in the −x direction, i.e., opposite to the other segments **212**A that are not in contact with the corneal surface **2**A and that are still moving toward the corneal surface **2**A. Although there may be a bias acting on the segments **212**A and **212**B in the +x direction, the reaction force in the −x direction is able to overcome the bias and cause movement of the segments **212**A and **212**B. As discussed previously, this bias promotes contact between the corneal surface **2**A and the segments **212**A and **212**B, but does not apply undesired levels of pressure as the segments **212**A and **212**B move against the bias. The energy conducting element **211** is moved until all the segments **212**A and **212**B are in contact with the corneal surface **2**A. The relative movement between the segments **212**A and **212**B allows the total contact surfaces **211**G and **211**H to change according to the shape of the corneal surface **2**A. Moreover, the relative movement allows the contact and pressure applied by the energy conducting element **211** to be more uniform. Accordingly, as illustrated by the embodiment of FIGS. **3**A-C, aspects of the present invention provide a self-adjusting applicator that promotes desired contact with more uniform pressure. Once the appropriate contact has been achieved between the total contact surfaces **211**G and **211**H and the corneal surface **2**A, energy can be delivered, via the conductors **211**A and **211**B, to the cornea **2** in the desired reshaping pattern.

As shown further in FIGS. **3**A and **3**C, the segments **212**A extend from the distal end **210**B to the intermediate section **210**D of the outer conductor **211**A where they may be electrically connected by a coupling **211**I. Likewise, the segments **212**B extend from the distal end **210**B to the intermediate section **210**D of the inner conductor **211**B where they may be electrically connected by a coupling **211**J. The couplings **211**I and **211**J may be formed of a conductive material, such as those described previously, and facilitate the delivery of energy from the energy source **220** to the segments **212**A and **212**B, respectively. When moving along the longitudinal axis **210**C, the segments **212**A and **212**B may, for example, slide within openings in the corresponding couplings **211**I and **211**J while remaining in conductive contact with the couplings **211**I and **211**J. Alternatively, **211**I or **2121**J may be flexible and may bend as the segments **212**A or **212**B slide up or down.

There are significant additional advantages to having multiple, individually adjustable outer conductor segments **212**A and/or inner conductor segments **212**B. In particular, a system including multiple, individually adjustable outer conductor segments **212**A and/or inner conductor segments **212**B can be selectively configured by raising and/or lowering the individual segments **212**A and **212**B to provide energy to the cornea **2** according to a desired penetration depth and/or pattern.

The penetration depth of the energy into the cornea **2** is determined, in part, by the distance of the gap **211**C between the outer conductor **211**A and the inner conductor **211**B. If, for example, the inner row of segments **212**A of the outer conductor **211**A is raised and no longer makes direct contact with the cornea surface **2**A, only the outer ring of segments **212**A of the outer conductor **211**A will be in contact with the cornea surface **2**A and the gap **211**C will be widened between the inner conductor **211**B and outer conductor **211**A at or near the cornea surface **2**A. Similarly, if the outer row(s) of segments **212**B of the inner conductor **211**B is raised and no longer makes direct contact with the cornea surface **2**A, only the inner ring(s) of segments **212**B of the inner conductor **211**B will be in contact with the cornea surface **2**A and the gap **211**C will also be widened between the inner conductor **211**B and the outer conductor **211**A at or near the cornea surface **2**A. This variation in the distance of the gap **211**C affects the penetration depth of microwave energy into the cornea **2**, influencing the resulting lesion. Accordingly, the distance of the gap **211**C (and thus the penetration depth) can be controlled by selectively raising one or more of the inner rows of the outer conductor segments **212**A and/or one or more of the outer rows of the inner conductor segments **212**B.

While FIGS. **3**A-**3**C illustrate the outer conductor **211**A having two rows of outer conductor segments **212**A and the inner conductor **211**B having six rows of inner conductor segments **212**B, any other number of rows of outer conductor segments **212**A or inner conductor segments **212**B can be provided. The greater the number of rows of segments **212**A and **212**B provided, the greater the flexibility provided for selection of the distance of the gap **211**C.

The pattern of energy applied to the cornea **2** is determined, in part, by the contact surfaces **211**G and **211**H at or near the cornea surface **2**A. By selectively controlling the elevation of the individual segments **212**A and **212**B relative to the cornea surface **2**A, various effective contact surface **211**G and **211**H configurations can be achieved.

For example, if only the outer ring of conductor segments **212**B of the inner conductor **211**B is in contact with the cornea surface **2**A, the heating pattern will be based on a ring shaped inner conductor. If a smaller ring of conductor segments **212**B is left in contact with the cornea surface **2**A due to the elevation of the remaining conductor segments **212**B, the heating zone will be a smaller ring.

As another example, if some part of the circumference (e.g., 90-180°) of the outer conductor **211**A is raised and no longer contacts cornea surface **2**A (i.e., both the inner row and the outer row of the outer conductor segments **212**A are raised at a part of the circumference), the heating zone will be biased away from the noncontact region.

As still another example, if only one to ten individual, non-neighbor, conductor segments **212**B of the inner conductor **211**B are lowered onto the cornea surface, individual spot treatments due to the individual conductor contact will result. And if, for example, two to five neighbor conductor segments

212B are lowered into contact with the cornea, a larger, well-defined region will be treated. Such spot treatments may be useful to treat particular disorders such as, for example, astigmatism.

Additional examples of non-annular energy patterns, which may be formed by the conductor segments **212**A and **212**B are described in U.S. patent application Ser. No. 12/113,672, filed on May 1, 2008, the contents of which is entirely incorporated herein by reference.

To achieve various configurations of the outer conductor segments **212**A and the inner conductor segments **212**B, electrical and/or mechanical devices may be employed to raise, lower, and/or lock individual conductor segments **212**A and **212**B at various elevations relative to the cornea surface **2**A. For example, each conductor segment **212**A and **212**B can be coupled to an actuator device in addition to or instead of the biasing devices described above. The actuator devices can be any devices capable of moving conductor segments **212**A and **212**B in the −x and/or +x direction along the longitudinal axis **210**C. Nonlimiting examples of suitable actuator devices include electrical motors, pneumatic actuators, hydraulic pistons, relays, electroactive polymers, combinations thereof, and/or any other transducer device. The actuator devices can be further coupled to a controller for providing automated control of the elevation of the segments **212**A and **212**B relative to the cornea surface **2**A. Optionally, a locking mechanism can be employed to ensure that the segments **212**A and **212**B are locked at a specific elevation relative to the cornea surface **2**A after the actuator device has moved the segments **212**A and **212**B into the appropriate position.

According to one embodiment, a particular configuration of the conductor segments **212**A and **212**B can be achieved by first moving all segments **212**A and **212**B into contact with the cornea surface **2**A to achieve uniform pressure as described above and then raising specific segments **212**A and **212**B to one or more elevations above the cornea surface **2**A. Alternatively, a particular configuration of conductor segments **212**A and **212**B can be achieved by first moving specific segments **212**A and **212**B to one or more raised positions and then moving the remaining segments **212**A and **212**B into contact with the cornea surface **2**A to achieve uniform pressure over the remaining segments **212**A and **212**B.

There are still further advantages to a system having multiple outer conductor segments **212**A and inner conductor segments **212**B. For example, a system having multiple outer conductor segments **212**A and inner conductor segments **212**B also advantageously allows for selective application of energy through the individual segments **212**A and/or **212**B to the cornea **2**. In other words, energy can be applied to the cornea **2** by some segments **212**A and **212**B but not other segments **212**A and **212**B. Accordingly, the depth of penetration can be selectively configured by activating or deactivating conductor segments **212**A and **212**B to achieve a selected distance for the gap **211**C. Likewise, a pattern of energy applied to the cornea can be selectively configured by activating or deactivating the individual segments **212**A and **212**B.

To selectively apply energy to individual segments **212**A and/or **212**B, each of the segments **212**A and **212**B is individually coupled to the energy source **220**. In operation, electrical energy from the energy source **220** can be conducted from the proximal end **210**A to the distal end **210**B via the outer conductor segments **212**A and inner conductor segments **212**B that are activated. According to some embodiments, a controller can be employed to select and activate the conductor segments **212**A and **212**B. Additionally, a dielectric material may be disposed between neighbor (i.e., adjacent) segments to prevent or inhibit conduction of electrical current between the conductors **212**A and **212**B. In some embodiments, the dielectric material may be formed as a part of sheath-like structures positioned over the outer surface of the conductors **212**A-B.

Additional details and advantages associated with selectively activating and deactivating particular segments **212**A and **212**B are described in a U.S. Non-Provisional Application that is being concurrently filed, which claims the benefit of priority from U.S. Provisional Application No. 61/166,009, filed Apr. 2, 2009, the entire contents of which are hereby incorporated by reference.

It is contemplated that each conductor segment **212**A and/or **212**B can be activated/deactivated when positioned in an elevated position relative to the cornea surface **2**A, or when positioned in contact with the cornea surface **2**A. Thus, the depth of penetration and/or the pattern of energy applied to the cornea can be controlled by selectively configuring the elevation of the conductor segments **212**A and **212**B and/or selectively activating or deactivating the conductor segments **212**A and **212**B.

Accordingly, the applicator **210** provides a single convenient and versatile tool that allows an operator to apply energy to the cornea according to different patterns and different penetration depths to suit different treatment cases, without requiring multiple applicators or interchangeable components. Although the applicator **210** may be employed for a single application of energy according to a single outer conductor/inner conductor pair, the applicator **210** may be particularly advantageous when multiple applications of energy according to multiple patterns are required to achieve the desired change in the shape of the cornea. For example, energy is incrementally applied to the cornea in precise and measured steps in multiple ring-shaped patterns. An example of a multi-step approach is described in U.S. patent application Ser. No. 61/098,489, filed on Sep. 19, 2008, the contents of which are entirely incorporated herein by reference. In general, energy may be applied multiple times according to different patterns and pulses, i.e., duration and magnitude, to achieve the desired shape change. Indeed, in some embodiments, an asymmetric shape change, for example to treat astigmatism, may be effected by multiple applications of energy in different ring-shaped patterns that are centered at different areas of the cornea.

While the conductor segments **212**A and **212**B illustrated in FIGS. **3**A-**3**C were formed as cylindrical or pin-like structures, it is contemplated that in other embodiments, the segments can have any suitable shape or size. For example, according to the alternative embodiments illustrated in FIGS. **4**A-D, the conductors **311**A-B, **411**A-B, **511**B and **611**B may include segments that are formed as discrete sectors or sections of a cylinder. It is further contemplated that in some embodiments, the segments may include a combination of different shapes and sizes.

Although embodiments above may refer to one energy source and to one controller, it is understood that more than one respective energy source and/or more than one controller may be employed to operate an applicator according to aspects of the present invention. For example, referring to the embodiment of FIG. **3**, each of the conductor segments **212**A-B may be coupled to a dedicated energy source. The conductors segments **212**A-B and their respective energy sources may be selectively activated by one controller. Alternatively, each of the conductors segments **212**A-B may each be selectively activated by a dedicated controller. In general, any number of conductors or conductor segments may be coupled to any number of energy sources and any number of controllers to deliver an appropriate amount energy for an appropriate duration according to a desired pattern.

Furthermore, the controller(s) described above may be a programmable processing device that executes software, or stored instructions, and that may be operably connected to the other devices described above. In general, physical processors and/or machines employed by embodiments of the present invention for any processing or evaluation may include one or more networked or non-networked general purpose computer systems, microprocessors, field programmable gate arrays (FPGAs), digital signal processors (DSPs), micro-controllers, and the like, programmed according to the teachings of the exemplary embodiments of the present invention, as is appreciated by those skilled in the computer and software arts. The physical processors and/or machines may be externally networked with the image capture device, or may be integrated to reside within the image capture device. Appropriate software can be readily prepared by programmers of ordinary skill based on the teachings of the exemplary embodiments, as is appreciated by those skilled in the software art. In addition, the devices and subsystems of the exemplary embodiments can be implemented by the preparation of application-specific integrated circuits (ASICs) or by interconnecting an appropriate network of conventional component circuits, as is appreciated by those skilled in the electrical art(s). Thus, the exemplary embodiments are not limited to any specific combination of hardware circuitry and/or software.

Stored on any one or on a combination of computer readable media, the exemplary embodiments of the present invention may include software for controlling the devices and subsystems of the exemplary embodiments, for driving the devices and subsystems of the exemplary embodiments, for enabling the devices and subsystems of the exemplary embodiments to interact with a human user, and the like. Such software can include, but is not limited to, device drivers, firmware, operating systems, development tools, applications software, and the like. Such computer readable media further can include the computer program product of an embodiment of the present inventions for performing all or a portion (if processing is distributed) of the processing performed in implementing the inventions. Computer code devices of the exemplary embodiments of the present inventions can include any suitable interpretable or executable code mechanism, including but not limited to scripts, interpretable programs, dynamic link libraries (DLLs), Java classes and applets, complete executable programs, and the like. Moreover, parts of the processing of the exemplary embodiments of the present inventions can be distributed for better performance, reliability, cost, and the like.

Common forms of computer-readable media may include, for example, a floppy disk, a flexible disk, hard disk, magnetic tape, any other suitable magnetic medium, a CD-ROM, CDRW, DVD, any other suitable optical medium, punch cards, paper tape, optical mark sheets, any other suitable physical medium with patterns of holes or other optically recognizable indicia, a RAM, a PROM, an EPROM, a FLASH-EPROM, any other suitable memory chip or cartridge, a carrier wave or any other suitable medium from which a computer can read.

Although the embodiments described above are applied to a cornea, other embodiments may be applied to other features of an eye.

While the present invention has been described in connection with a number of exemplary embodiments, and implementations, the present inventions are not so limited, but rather cover various modifications, and equivalent arrangements.

We claim:

1. A system for applying thermokeratoplasty to an eye, the system comprising:

- an electrical energy source; and
- an electrical energy conducting element extending from a proximal end to a distal end, the energy conducting element electrically connected to the electrical energy source at the proximal end, the energy conducting element including:
  - an outer conductor extending to the distal end, the outer conductor including a plurality of moveable outer segments; and
  - an inner conductor extending to the distal end and disposed within the outer conductor, the inner conductor including a plurality of moveable inner segments, the outer conductor and the inner conductor being separated by a gap, the plurality of outer segments and the plurality of inner segments forming a total contact surface at the distal end, the total contact surface being positionable at a corneal surface of an eye such that an energy is applied to the eye according to the total contact surface to cause shrinkage of corneal tissue of the eye in response to the electrical connection between the energy conducting element and the electrical energy source,
  - wherein each of the plurality of outer segments is individually and separately moveable and each of the plurality of inner segments is individually and separately moveable.

2. The system of claim **1**, wherein the total contact surface corresponds to the shape of a cornea.

3. The system of claim **1**, wherein the plurality of outer segments and the plurality of inner segments are operable to adjust to the shape of the eye.

4. The system of claim **1**, wherein the plurality of outer segments and the plurality of inner segments extend from an intermediate section of the conducting element to the distal end, the intermediate section being between the proximal end and the distal end.

5. The system of claim **4**, wherein the plurality of outer conductors and the plurality of inner conductors are connected to the intermediate section by one or more coupling devices.

6. The system of claim **1** further comprising at least one biasing member, the at least one biasing member biasing the plurality of outer segments and the plurality of inner segments towards the distal end.

7. The system of claim **1**, wherein the plurality of outer segments and the plurality of inner segments are substantially cylindrical at the distal end.

8. The system of claim **1**, wherein the plurality of outer segments and the plurality of inner segments are moveable between the proximal end and the distal end.

9. The system of claim **1**, wherein at least one of the outer segments and at least one of the inner segments are operable to be fixed at one or more positions between the proximal end and the distal end.

10. The system of claim **9**, wherein the position at which the at least one outer segment and the at least one inner segment are fixed is dependent upon a pattern of energy to be applied to the eye.

11. The system of claim **10**, wherein the pattern is asymmetric.

12. The system of claim **9**, wherein the position at which the at least one outer segment and the at least one inner segment are fixed is dependent upon a selected depth of penetration of the energy to be applied to the eye.

13. The system of claim **1**, wherein the gap is a substantially annular gap.

14. The system of claim **1** further comprising a controller configured to control the supply of electrical energy to each outer segment and each inner segment, each outer segment and each inner segment being individually coupled to the electrical energy source.

15. The system of claim **1**, wherein each outer segment is spaced apart from each adjacent outer segment such that the plurality of outer segments collectively act as a single outer conductor and each inner segment is spaced apart from each adjacent inner segment such that the plurality of inner segments collectively act as a single inner conductor.

16. The system of claim **1** further comprising a layer of dielectric material disposed on at least a portion of the total contact surface, the layer of dielectric material being configured to substantially inhibit an electrical current from the inner conductor and the outer conductor into the corneal tissue while allowing a microwave heating pattern to be applied to the eye according to the total contact surface to cause shrinkage of corneal tissue of the eye in response to the electrical connection between the energy conducting element and the electrical energy source.

17. A method for applying thermokeratoplasty to an eye, the method comprising:

positioning a total contact surface of an electrical energy conducting element at a corneal surface of an eye, the energy conducting element being operably connected to an electrical energy source at a proximal end and extending to the total contact surface at a distal end, the energy conducting element including:

an outer conductor extending to the distal end, the outer conductor including a plurality of moveable outer segments; and

an inner conductor extending to the distal end and disposed within the outer conductor, the inner conductor including a plurality of moveable inner segments, the outer conductor and the inner conductor being separated by a gap, the plurality of outer segments and the plurality of inner segments forming the total contact surface at the distal end; and

applying energy from the electrical energy conducting element to the eye according to the total contact surface to cause shrinkage of corneal tissue of the eye,

wherein each of the plurality of outer segments is individually and separately moveable and each of the plurality of inner segments is individually and separately moveable.

18. The method of claim **17**, wherein the total contact surface corresponds to the shape of a cornea.

19. The method of claim **17**, wherein the plurality of outer segments and the plurality of inner segments are operable to adjust to the shape of the eye.

20. The method of claim **17**, wherein the contact surface is positioned at the eye such that the contact surface applies a uniform pressure on the eye.

21. The method of claim **17**, wherein the electrical energy conducting unit includes at least one biasing member, the at least one biasing member biasing the plurality of outer segments and the plurality of inner segments towards the distal end.

22. The method of claim **17**, wherein the plurality of outer segments and the plurality of inner segments are substantially cylindrical at the distal end.

23. The method of claim **17** further comprising moving at least one outer segment to a position between the distal end and the proximal end.

24. The method of claim **23**, wherein the position is selected such that the at least one outer segment does not contact the eye.

25. The method of claim **17** further comprising moving at least one inner segment to a position between the distal end and the proximal end.

26. The method of claim **25**, wherein the position is selected such that the at least one inner segment does not contact the eye.

27. The method of claim **17** further comprising moving at least one outer segment and at least one inner segment to achieve at least one of the group consisting of a selected pattern of energy applied to the eye and a selected depth of penetration of energy into the eye.

28. The method of claim **27**, wherein the pattern is asymmetric.

29. The method of claim **17** further comprising supplying energy from the electrical energy source to one or more outer segments and one or more inner segments.

30. The method of claim **29**, wherein the energy is not supplied to at least one outer segment.

31. The method of claim **29**, wherein the energy is not supplied to at least one inner segment.

32. The method of claim **17** further comprising selectively supplying energy to at least one outer segment and at least one inner segment to apply energy to a cornea according to an asymmetric pattern.

33. A system for applying thermokeratoplasty to an eye, the system comprising:

an electrical energy source; and

an electrical energy conducting element extending from a proximal end to a distal end, the energy conducting element electrically connected to the electrical energy source at the proximal end, the energy conducting element including:

an outer conductor extending along a longitudinal axis to the distal end, the longitudinal axis being generally in a direction from the proximal end to the distal end, the outer conductor having an interior surface, the outer conductor including a plurality of moveable outer segments, the plurality of moveable outer segments being configured to be individually and separately moveable along the longitudinal axis;

an inner conductor extending along the longitudinal axis to the distal end and disposed within the outer conductor, the inner conductor including a plurality of moveable inner segments, the plurality of moveable inner segments are configured to be individually and separately moveable along the longitudinal axis, the inner conductor having an exterior surface separated from the interior surface of the outer conductor by a gap, the gap extending entirely around the exterior surface of the inner conductor; and

a flexible sheath-like structure of dielectric material covering the distal end configured to substantially inhibit an electrical current from the inner conductor and the outer conductor into the corneal tissue, the plurality of outer segments and the plurality of inner segments forming a total contact surface at the distal end, the total contact surface being positionable at a corneal surface of an eye such that a microwave energy is applied to the eye according to the total contact surface to cause shrinkage of corneal tissue of the eye in response to the electrical connection between the energy conducting element and the electrical energy source.

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